

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE ORGANOGENESIS SECURITIES LITIGATION

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) No. 04-10027-JLT
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**DEFENDANT HERBERT M. STEIN'S REPLY MEMORANDUM
TO LEAD PLAINTIFFS' CONSOLIDATED OPPOSITION TO
THE INDIVIDUAL DEFENDANTS' MOTIONS TO DISMISS**

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INTRODUCTION

Lead Plaintiffs' Consolidated Opposition to the Individual Defendants' Motions to Dismiss ("Plaintiffs' Opposition") provides no persuasive argument why their allegations against Mr. Stein, who was only associated with Organogenesis for the first couple of months of the over two year long class period, are sufficient to state a claim under Section 10(b) or Section 20(a) of the Securities Exchange Act. 15 U.S.C. §§ 78j(b), 78t(a). Instead of directly addressing or contesting Mr. Stein's arguments, Plaintiffs' Opposition purposefully blurs the line between Mr. Stein and the other defendants and their alleged statements -- almost all of which were made only after Mr. Stein left the Company.

The Opposition also obfuscates the chronology of the various alleged statements and fails to identify when the alleged "material adverse factors" supposedly came into existence. Plaintiffs' failure to allege such a chronology of events is especially fatal to their case against Mr. Stein because, as discussed above, he was only affiliated with Organogenesis for the first couple of months of the class period.

Furthermore, Plaintiffs do not even attempt to rebut Mr. Stein's numerous citations to decisions from this District holding that statements nearly identical to those that he allegedly made are not actionable. Plaintiffs also fail to plead sufficient facts to allow their allegations based on informants to stand. Finally, Plaintiffs do not even attempt to distinguish the First Circuit decision Mr. Stein relies on to show that any registration or sale of stock he allegedly made upon leaving the Company does not, as a matter of law, raise any inference of scienter.

It is clear why Plaintiffs have failed to engage Mr. Stein's arguments. When Mr. Stein's alleged statements are extracted from the puzzle-like Complaint, and analyzed one-by-one, as is required in this Circuit, see Carney v. Cambridge Tech. Partners, Inc., 135 F. Supp. 2d 235, 243 (D. Mass. 2001), Plaintiffs' claims against him turn out to be wholly inadequate. Plaintiffs' Opposition heavily relies on the alleged "Confidential Arcari Document," and the alleged "Novartis Put

Option.” While neither of these two documents are sufficient against any of the defendants, they are certainly inapplicable to Mr. Stein because he is alleged to have left Organogenesis long before these documents came into existence.

Another failing of Plaintiffs’ Opposition is that it contains sparse citations to courts in this Circuit or in this District for authority on many of its arguments. The Opposition primarily cites to decisions outside of this jurisdiction, and even cites to several decisions that came out before the PSLRA changed the pleading requirements in securities fraud cases. The cases from this Circuit and District that the Opposition does manage to cite mostly involve allegations of massive accounting fraud -- something that Plaintiffs have not alleged in this case. One First Circuit decisions that Plaintiffs cite actually supports Mr. Stein’s motion to dismiss. In Serabian v. Amoskeag Bank Shares, Inc., 24 F.3d 357, 368 n.17 (1st Cir. 1994) the First Circuit dismissed all claims against the company’s former CEO and Chairman of the Board because he resigned from his positions approximately halfway through the class period, and before any actionable statements were made.

The Opposition’s use of authority is in marked contrast to the recent decisions within this jurisdiction and involving the biotech industry cited by Mr. Stein in his Memorandum in Support of his Motion to Dismiss (“Stein Memorandum”).¹ It should be noted that the biotech industry presents unique factual settings for securities cases, and this District is at the forefront in developing the securities law in this area.

The Supreme Court recently reminded plaintiffs that the securities laws are not meant “to provide investors with broad insurance against market losses.” Dura Pharm., Inc. v. Broudo, 125 S. Ct. 1627, 1633 (2005).² When Plaintiffs’ arguments are examined closely, it is clear that their claims against Mr. Stein are nothing more than an impermissible attempt to insure their investment.

¹ Mr. Stein filed his Motion to Dismiss and the Accompanying Memorandum in Support on January 14, 2005.

² The Dura case involved the concept of loss causation in the securities fraud context. The Court held that alleging a purchase at an inflated price alone did not satisfy the loss causation standard. Rather, to prove the requisite proximate

I. The Plaintiffs Fail to Meet Numerous Dispositive Issues.

The Plaintiffs' Opposition attempts to direct this Court's attention away from the requisite statement-by-statement analysis provided in Mr. Stein's Memorandum, (Stein Memo., pp. 7-15), which demonstrated how none of his alleged statements were actionable as a matter of law. The Plaintiffs have engaged in this misdirection because they cannot persuasively oppose Mr. Stein's arguments based on these dispositive issues.

A. Mr. Stein's Alleged Statements Are Inactionable For Several Independent Reasons.

Plaintiffs failed to meet the following arguments made in Mr. Stein's Memorandum demonstrating that, as a matter of law, Mr. Stein's alleged statements are not actionable.

Alleged Statement	Source	Dispositive Issues Not Contested	Cite to Mr. Stein's Memorandum
"We expect Apligraf commercial sales to increase."	11/15/99 10-Q	<ul style="list-style-type: none"> Plaintiffs fail to explain why an accurate projection of a future result is actionable. Even if not accurate, such soft expectations are inactionable puffery. Plaintiffs have failed to allege that at the time Mr. Stein made this statement (on the first day of the class period) that any of the alleged "material adverse factors" were in existence. The statement is inactionable due to the numerous and specific risk factors disclosed about acceptance of the product. 	Pages 13-15

cause between an alleged misrepresentation and a subsequent economic loss, plaintiffs must "provide[] the defendants with notice of what the relevant economic loss may be or of what the causal connection might be between that loss and the misrepresentation..." 125 S. Ct at 1634. It should be noted that Plaintiffs in this case have failed to meet this requirement. Just as the plaintiffs did in Dura, Plaintiffs in this case allege a purchase at an inflated price. (Compl. ¶21). They then seem to allege that their economic loss occurred as a result of a January 30, 2002 disclosure by Organogenesis regarding its inability to exercise the Novartis Put Option, which in turn created a liquidity crisis. (Compl. ¶¶ 14,150-51). But this disclosure, which allegedly caused the loss, has nothing to do with the alleged omissions made by Mr. Stein two years earlier because the Novartis Put Option did not exist during Mr. Stein's tenure at Organogenesis, and Mr. Stein fully disclosed the future uncertainty of the Company's liquidity. (Stein Memo., p. 2). Not only is there a glaring lack of causation between Mr. Stein's alleged statements and Plaintiffs' allegations regarding their ultimate economic loss, but the fact that Mr. Stein left Organogenesis approximately two full years before the alleged loss is another important factor that undercuts any allegations that Mr. Stein's alleged statements caused any economic loss. Id. at 1631 ("[o]ther things being equal, the longer the time between purchase and sale, the more likely that other factors caused the loss").

Alleged Statement	Source	Dispositive Issues Not Contested	Cite to Mr. Stein's Memorandum
"We expect to continue to expand manufacturing operations."	11/15/99 10-Q	<ul style="list-style-type: none"> Plaintiffs fail to explain why an accurate projection of a future result is actionable. Even if not accurate, such soft expectations are inactionable puffery. Plaintiffs have failed to allege that at the time Mr. Stein made this statement (on the first day of the class period) that any of the alleged "material adverse factors" were in existence. The statement is inactionable due to the numerous and specific risk factors disclosed about acceptance of the product. 	Pages 13-15
Apligraf is "well-received by physicians."	11/15/99 Press Release	<ul style="list-style-type: none"> Plaintiffs fail to make any allegations at all that <u>at the time this statement was made</u> the alleged "material adverse factors" relating to Apligraf's acceptance were in existence. Plaintiffs fail to explain why this statement was false given the 400% increase in sales in Apligraf throughout the rest of the class period. Such general, "soft" statements about a product's demand are mere puffery and inactionable as being immaterial. The statement is inactionable due to the numerous and specific risk factors disclosed about acceptance of the product. 	Pages 7-9
"The key remaining piece of the puzzle is gaining broad, standardized reimbursement. Achieving standardized reimbursement for Apligraf is a top priority at both Novartis and Organogenesis and is being addressed aggressively by both Companies."	11/15/99 Press Release	<ul style="list-style-type: none"> Plaintiffs provide no specific allegations as to why this statement is false. In fact, in Plaintiffs' Chart titled "Individual Defendants' Misrepresentations and Omissions"³ that accompanies their Opposition, Plaintiffs specifically omit this statement from those they are allegedly basing their claims upon. 	Pages 9-11

Because each of these statements are not actionable for each of the several distinct reasons described above, and because Plaintiffs have not even attempted to meet these reasons, Plaintiffs' claims against Mr. Stein cannot be based on any of these alleged statements.

B. Plaintiffs Fail to Address Their Inadequate Use of Informants.

Another independent basis requiring dismissal of the counts against Mr. Stein stems from Plaintiffs' failure to meet Mr. Stein's arguments regarding the inadequacy of the allegations in the

³ Hereinafter referred to as "Chart."

Complaint attributed to informants. This failure is significant because Plaintiffs almost exclusively rely on informants to support their allegations regarding the existence of various “material adverse factors.”

Many recent decisions have demonstrated an increasing reluctance to allow securities cases to proceed on the basis of rumors and disparaging remarks made by disgruntled ex-employees. See e.g., California Pub. Employees’ Ret. Sys. v. Chubb Corp., 394 F.3d 126 (3rd Cir. 2004); Freed v. Universal Health Services, Inc., No. Civ. A. 04-1233, 2005 WL 1030195 (E.D. Pa. May 3, 2005); In re Vertex Pharm., Inc., 357 F. Supp. 2d 343 (D. Mass. 2005). In fact, since Mr. Stein filed his Memorandum, the Vertex court in this District dismissed a complaint, like the one in this case, that relied on statements from informants as to the existence of alleged material adverse factors. 357 F. Supp. 2d at 354-55.

Even the authority Plaintiffs frequently cite makes it clear that the law relating to informants requires that a complaint allege proper facts to show that the informant’s allegations “provide an adequate basis for believing that the defendants’ statements were false.” In re Cabletron Sys., Inc., 311 F.3d 11, 29 (1st Cir. 2002) (citing Novak v. Kasaks, 216 F.3d 300, 314 (2d Cir. 2000)). Included in this determination is a close review of “the level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia.” Id. at 29-30. Cabletron also required that plaintiffs describe an informant “with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged.” Id. at 29 (quoting Novak, 216 F. 3d at 314).

In applying this Cabletron and Novak standard, the Vertex court closely examined whether the informant was specifically alleged to be employed during the relevant time-frame. 357 F. Supp. 2d at 353. The Vertex court ended up refusing to rely on the informants because only one of the three informants “worked at Vertex during the entire duration of the Class Period.” Id.

Other courts have also required specific allegations of when the informant was allegedly employed, and how the informant allegedly obtained his or her knowledge. And these courts have also stated that reliance on an informant is improper, as a matter of law, when that informant is not specifically alleged to have been employed on the relevant date, or their source of knowledge is not sufficiently identified or apparent. Chubb, 394 F.3d at 148 (holding that reliance on informants was improper because plaintiff had failed to allege “when any of them were employed by Chubb” or “the dates that [they] acquired the information they purportedly possess”); Freed, 2005 WL 1030195 *6 (“complaints that rely heavily on confidential sources to establish the ‘true facts’ must contain information describing the time period during which the confidential sources were employed by the defendant corporation, the dates on which they acquired the information they purportedly possess, and the manner in which they had access to such information”) (emphasis added); In re Syncor Int’l Corp. Sec. Litig., 327 F. Supp. 2d 1149, 1158-59 (C.D. Cal. 2004) (holding that the failure to allege “job description, job title, dates of employment, and job responsibilities” rendered the allegations based on an informant insufficient) (emphasis added).

The informants relied on by Plaintiffs in this case are inadequate for four separate reasons: (a) the allegations fail to provide the informants’ periods of employment, (b) the allegations fail to provide the time that they acquired their knowledge, (c) the allegations are insufficient to show how the informants gained access to the information or knowledge, and (d) the allegations are too conclusory and lack any detail. The failures of Plaintiffs to specifically allege when the informants were employed and when they acquired their knowledge are especially relevant in this action against Mr. Stein because Mr. Stein’s alleged statements were all essentially made on the first day of the class period. The following chart describes how each of the informants relied upon by the Plaintiffs in their allegations against Mr. Stein are inadequate as a matter of law.

Informant and Allegation	Cite to Complaint	Why Informant Allegation is Inadequate As a Matter of Law
A “Senior Manager of Quality Systems Compliance stated that there was ‘no way’ that the Company could commercially mass-produce Apligraf...”	¶62(a)	<p>Timing: Plaintiffs fail to allege that this informant was employed or had the information on the first day of the class period when Mr. Stein allegedly made his statements.</p> <p>Access to Information: Plaintiffs rely on this informant in arguing that Mr. Stein’s alleged statements regarding production costs and margins are false. But plaintiffs fail to state how a “Senior Manager of Quality Systems Compliance” would have knowledge of or access to the financial data necessary to make an evaluation regarding production costs, margins, and the commercial feasibility of production.</p> <p>Conclusory Allegation: This allegation is short and conclusory and has no additional details supporting how this individual knew this “true fact.” Allegations along these lines are considered to be unreliable rumors. <u>See Chubb</u>, 394 F.3d at 155 (refusing to rely on broad conclusory allegations made by informants that certain facts were “well known” throughout Chubb because such statements amounted to mere rumors and speculation).</p>
A “Maintenance Supervisor” stated that the company “would ship the product before they had the results back from the QC lab.”	¶62(b)	<p>Timing: There is no allegation when this practice occurred or when this employee became aware of it.</p> <p>Access to Information: There are no allegations as to how this employee gained access to this information. The employee’s title actually undermines any presumption that he or she would have access to this type of information.</p> <p>Conclusory Allegation: This allegations contains no information on the “who, what, where, why, or when” of such shipments.</p>
A former employee of Novartis and a former contractor for Novartis alleged that physicians “grew frustrated” with Apligraf and “couldn’t rely on it coming through.”	¶62(c) & (d)	<p>Timing: There are no allegations as to when these two individuals were employed by Novartis, or when physicians expressed this alleged frustration, or even if or when these individuals, employed by Novartis, ever communicated their observations to anyone at Organogenesis. This issue of timing is especially critical in this case considering the fact that the allegation states that the physicians “grew frustrated,” which suggests that this alleged frustration developed over time, which would mean that when Mr. Stein made his statements regarding Apligraf on the first day of the class period, there was not an unusual level of frustration.</p>
A Project Engineer alleges that it was “well known by [] upper management” that Organogenesis was losing money on each unit of Apligraf sold, and a “Maintenance Supervisor” stated that the entire company knew.	¶65	<p>Timing: Again, there are no allegations as to when these individuals were employed, or when they knew this information, or even when all of “upper management” or the “whole company” knew.</p> <p>Access to Information: There are no allegations showing how employees in these positions would have access to the financial data needed to draw their conclusions.</p> <p>Conclusory Allegations: These types of conclusory allegations that the entire company knew of a certain fact have been held to be unreliable as a matter of law. <u>See Chubb</u>, 394 F.3d at 155 (refusing to rely on broad conclusory allegations made by informants that certain facts were “well known” throughout Chubb because such statements amounted to mere rumors and speculation).</p>

For each of these reasons, all of Plaintiffs’ allegations against Mr. Stein that rely on the use of informants cannot be used as a basis for any claims against him. Because Plaintiffs rely in whole or in part on informants for the “supporting evidence” of falsity in every single statement allegedly

attributable to Mr. Stein, (Chart, pp. 1-3), their failure to comply with applicable law in this area is an additional independent basis for why the claims against Mr. Stein must be dismissed.

II. Plaintiffs Fail to Make Any Convincing Argument That Their Allegations Against Mr. Stein Are Sufficient.

In their Opposition, Plaintiffs only explicitly contest, in part, Mr. Stein's arguments regarding two of his alleged statements. But these arguments fail to provide an adequate basis for any claims against Mr. Stein.

A. "Production costs exceeded product sales due to the start-up costs of new product introduction and the high costs associated with low volume production."

Plaintiffs argue that Organogenesis was not losing money because of start-up costs and low volume production, but rather because it was losing money on each unit of Apligraf sold under the Novartis marketing agreement. (Opposition, p.31; Chart, p. 1). Plaintiffs argue "that it was a virtual certainty that the Company would lose money on Apligraf under the Novartis marketing agreement." (Opposition, p. 55).⁴ They argue that the above statement led investors to believe that Organogenesis could be profitable if it achieved higher volume production. (Opposition, p. 31).

Despite these repetitive and circuitous arguments, Plaintiffs fail to describe with the requisite particularity why Organogenesis could have never made money under the Novartis marketing agreement -- they merely treat it as a truism and rest their arguments on the fully disclosed fact that Organogenesis was losing money on sales of Apligraf. As Mr. Stein stated in his Memorandum, Plaintiffs, at best, are impermissibly pleading fraud in the hindsight by using the fact

⁴ Plaintiffs' Opposition keeps circling back to the same deficient argument: that Organogenesis failed to disclose that it was losing money on each unit of Apligraf sold, and that it was not reimbursed for units not sold. The problem with Plaintiffs' argument regarding the Novartis Agreement is the fact that Organogenesis frequently and prominently disclosed the fact that it was losing money on Apligraf sales. Every Form 10-Q and Form 10-K published prior to and during the class period clearly shows that total production costs were well-above total product sales. For example, see Organogenesis Form 10-Q, August 16, 1999, at 4, 9, 11 (Stein Appendix, Tab E); Organogenesis Form 10-Q, November 15, 1999, at 4, 9, 11. (Stein Appendix, Tab G). Plaintiffs seem to be in denial that these disclosures were made. Plaintiffs also allege that it was never disclosed that Novartis would not reimburse Organogenesis for Apligraf units that Organogenesis made, but Novartis did not sell. But this allegations has no merit because the Novartis Agreement itself, which was attached to the March 29, 1996 10-K, states that Novartis would only pay Organogenesis a royalty on "net sales" of Apligraf.

that Organogenesis was not ultimately able to make a profit in order to argue that Mr. Stein, on the very first day of the class period and over two years before Organogenesis filed for bankruptcy, was aware of this fact. (Stein Memo., p. 13, n.19).

Another fatal flaw to Plaintiffs' argument is the fact that Organogenesis' disclosures explicitly warned against this type of expectation. For example, Organogenesis stated that:

- “[W]ith increasing demand for Apligraf, we must further transition from small-scale to full-scale production of our products. If we do not make the full transition successfully, we will not be able to satisfy the demands for our products and our results of operations will be hurt.” Organogenesis Form 10-K, March 31, 1999, at 10 (Stein Appendix, Tab C)⁵;
- “There can be no assurance that the Company will realize sufficient production volume or otherwise reduce its production costs to significantly improve gross margins.” Organogenesis Form 10-Q, November 16, 1998, at 10 (Stein Appendix, Tab B);
- The Company faced the risk of not being able to have “manufacture and sale of products in sufficient volume to realize a satisfactory margin.” Organogenesis Form 10-Q, November 15, 1999, at 15 (Stein Appendix, Tab G); and
- It is possible that it “will be difficult to develop [our products] into commercially-viable products, [it] will be difficult to manufacture [our products] on a large scale.” Organogenesis Form S-3, May 17, 1999, at 4 (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999, at 6 (same) (Stein Appendix, Tab H).

Plaintiffs' argument that this statement was misleading also fails because Plaintiffs have made no allegations as to why Organogenesis would not have been able to lower production costs through higher volume production so that they could make a profit under the revenue split with Novartis. (See infra Part II.B below for a discussion of the inadequacy of Plaintiffs' allegations and arguments about Organogenesis' margins).

Plaintiffs have also failed to allege -- because they cannot -- that “high production costs” did not have any impact on the fully disclosed fact that Organogenesis was losing money on Apligraf sales. This failure is fatal to Plaintiffs' claims. See In re Cytyc, Civ. A. No. 02-12399, slip op. at 54-56 (D. Mass. March 1, 2005). In Cytyc, plaintiffs alleged that a statement describing how a

⁵ The cite to “Stein Appendix, Tab _” refers to the appendix Mr. Stein submitted with his memo on January 14, 2005.

company's growth was "driven by [its] proven market strategy, best-in-class sales team and superior technology" was misleading because it was actually undisclosed channel stuffing that fueled this illusion of "growth." Id. at 54. In finding the statement inactionable, as a matter of law, the Cytec court stated that plaintiffs failed to allege that "the market strategy or sales team or superior technology is not without any positive impact on Cytec's performance." Id.

During its discussion of this inactionable statement, the Cytec court cited Orton v. Parametric Tech. Corp., 344 F. Supp. 2d 290, 299 (D. Mass. 2004) in support of its position. The court in Parametric considered a similar issue where plaintiffs alleged a statement attributing strong financial results to various business decisions was misleading because the "success" was actually due to improper revenue recognition. Parametric, 344 F. Supp. 2d at 300. The Parametric court held that the statement was not misleading because plaintiffs had failed to allege that Parametric's business decisions had no positive impact on its performance. Id.

Furthermore, statements explaining the reasons for certain results are not actionable unless they purport to offer an exhaustive list of all the reasons for the success or growth. In re Boston Tech., Inc. Sec. Litig., 8 F. Supp. 2d 43, 69 (D. Mass. 1998) ("paragraph B is not reasonably construed to attribute the shortfall to an exclusive cause, and it was therefore immaterial to the investment decision"). Furthermore, "[s]tatements discussing how some market factors (like mergers among retail drug chains) are affecting business are not false and misleading simply because they do not implicate other negative market influences as well." In re Polaroid Corp. Sec. Litig., 134 F. Supp. 2d 176, 185 (D. Mass. 2001).

Therefore, under this principle described in Cytec, Parametric, Boston Tech., and Polaroid, Plaintiffs in this case cannot prevail by merely claiming that some other reason besides the high costs of production was responsible for Organogenesis' losses, but they must also allege that the high costs of production had absolutely no impact on the negative results. And this is something the Plaintiffs have failed to do.

B. “We expect production volume to increase and our margins to improve.”

Plaintiffs argue that this statement was misleading because an informant said there was “no way” Organogenesis could mass-produce Apligraf, and because Organogenesis was losing money on sales of Apligraf. (Chart, p. 1).

What Plaintiffs have failed to meet, however, is Mr. Stein’s argument that such projections are inactionable puffery, and such soft predictions that turn out to be true are obviously not actionable either. Carney, 135 F. Supp. 2d at 244-45. In this case, Plaintiffs explicitly allege that Organogenesis increased Apligraf production throughout the class period. (Compl. ¶ 136). This allegation renders Mr. Stein’s soft prediction made on the very first day of the class period accurate. Plaintiffs also fail to provide any argument as to why the allegations made by the informant they rely on to allege that mass-production of Apligraf was not possible are sufficient considering the lack of specificity about the time of employment, the time of knowledge, and the manner of acquiring the knowledge. For these two reasons alone, this statement allegedly made by Mr. Stein cannot be considered misleading.

Furthermore, the fact that Organogenesis was historically losing money on sales of Apligraf -- a fact that was always prominently disclosed -- has nothing to do with whether, in the future, margins could be improved by lowering costs through higher-volume production. Plaintiffs therefore, cannot rely on the fully disclosed fact that Organogenesis was losing money on Apligraf sales to demonstrate that this alleged statement made by Mr. Stein regarding production volume was somehow misleading.

In other words, the expectation of improving margins in the future by lowering production costs has nothing to do with whether the company had historically been able to sell its product at a profit.⁶

⁶ A “margin” obviously refers to the difference between the cost of manufacturing and distributing a single unit of a product and the revenue earned for that unit. Margins will improve therefore, if revenue earned per unit increases, or costs per producing and distributing a unit decreases. It is also axiomatic that, in general, one way to reduce costs is

III. Plaintiffs' Attempts to Hold Mr. Stein Accountable for Alleged Statements He Did Not Make Must Fail.

The Complaint clearly indicates that the Plaintiffs are only proceeding against Mr. Stein based on alleged statements he made in the November 15, 1999 10-Q, and the accompanying November 15, 1999 Press Release. (Compl. ¶¶68, 70). In fact, the Plaintiffs concede this fact in the early part of their Opposition. (Opposition, p. 17). Because Mr. Stein has already demonstrated why the allegations in those paragraphs have failed to state a claim against him, they will not be addressed any further.

But plaintiffs, potentially anticipating the inadequacy of their allegations against Mr. Stein, change their story at the end of their Opposition, and seem to argue that Mr. Stein should be accountable for additional alleged statements besides the ones identified in the Complaint and the ones identified in the previous section of their own Opposition. (Opposition, p. 54). Plaintiffs seem to rely on the "group-published doctrine" to hold Mr. Stein accountable for statements made in the December 2, 1999 Press Release, the February 14, 2000 Amended Form 10-Q, and the February 24, 2000 Press Release. (Opposition, p. 54). But then in their Chart, Plaintiffs back off from this argument and only seek to hold Mr. Stein accountable for one alleged statement made in the February 24, 2000 Press Release. In short, Plaintiffs' inability to consistently identify which statements they are alleging against Mr. Stein fails to provide Mr. Stein with adequate notice -- even under a Rule 8 standard -- as to the claims against him.

The Rule 8 issue aside, Plaintiffs have incorrectly relied on the "group-published" doctrine in their attempt to make any possible allegation against Mr. Stein stick. In limited circumstances, the "group-published" doctrine allows plaintiffs to hold company insiders accountable for

through higher-volume production. So if Organogenesis was able to reduce its manufacturing costs through higher volume production, its margins would improve. Because Plaintiffs have not even attempted to allege that higher volume production would not have lowered the cost of production, they cannot claim that Mr. Stein's alleged statement was misleading. Plaintiffs' argument that Organogenesis was losing money on Apligraf sales does not effect the discrete alleged statement relating to the margin between cost of production and revenue earned.

statements that were made in “group-published” materials, such as SEC filings. See In re Raytheon Sec. Litig., 157 F. Supp. 2d 131, 152 (D. Mass. 2001).

But despite this doctrine, Plaintiffs must still provide “sufficiently particularized allegations that the individual officer knew about the fraud,” Raytheon, 157 F. Supp. 2d. at 152 (citing Serabian, 24 F.3d at 367-68), and “the Court must evaluate the allegations concerning each of the individual defendants.” Id. at 153. Furthermore, “[t]his doctrine does not, however, obviate the requirement that a court evaluate separately the allegations concerning the scienter of each of the individual defendants.” In re Lernout & Hauspie Sec. Litig., 208 F. Supp. 2d 74, 84 (D. Mass. 2002).

To invoke the “group-published” doctrine, plaintiffs must specifically allege “that each individual defendant is a clearly cognizable corporate insider with an active daily role in the relevant companies or transactions.” Id. (internal quotations and citations omitted). Merely pleading insider status in a conclusory fashion, as Plaintiffs have done in this case, is insufficient. Compare (Compl. ¶ 35) with Lernout & Hauspie, 208 F. Supp. 2d at 84-85 (finding group pleading was appropriate based on specific allegations as to each individual’s receipt of certain specific emails, review of specific letters or contracts, and a specific description of job responsibilities).

The group pleading doctrine provides little support for Plaintiffs’ allegations against Mr. Stein because, as discussed above, it does not allow Plaintiffs to bypass the requisite statement-by-statement analysis and individualized examination of scienter with respect to each defendant.

Second, Plaintiffs have failed to properly invoke the doctrine with respect to Mr. Stein. Plaintiffs have failed to make any -- let alone any sufficient -- particularized allegations specific to Mr. Stein’s daily role and involvement in the company. This failure to plead adequate facts prevents Plaintiffs from invoking the group-published doctrine in holding Mr. Stein accountable for alleged statements made in the December 2, 1999 Press Release, the February 14, 2000 Amended Form 10-Q, and the February 24, 2000 Press Release.

Additionally, in ¶ 31, the Complaint alleges that as of December 31, 1999 Mr. Stein resigned as CEO and stepped down as acting Chairman of the Board. There are no sufficiently particularized allegations that after this date Mr. Stein had any role in or involvement with the management of Organogenesis. Finally, Mr. Stein cannot be held liable under the “group-published” doctrine for statements explicitly made by and attributed to others. For example, plaintiffs cannot claim that Mr. Stein is liable for the alleged statement specifically made by and attributed to Mr. Tuck in the December 2, 1999 Press Release.

Even if Plaintiffs could somehow manipulate the group-published doctrine in order to hold Mr. Stein accountable for the additional alleged statements, those statements, for the reasons stated below and in Co-Defendant’s Memorandum, cannot form the basis of any claims.

A. December 2, 1999 Press Release: “Apligraf Sales Reached a Record Number in November 1999.”

This statement is not misleading as a matter of law because it is an accurate report of past results. Plaintiffs argue that it misled investors about future results, but this argument fails because “reports of past successes do not themselves give rise to a duty to inform the market whenever present circumstances suggest that the future may bring a turn for the worse.” In re Parametric Tech. Corp., 300 F. Supp. 2d 206, 214 n.8 (D. Mass. 2001) (quoting Shaw v. Digital Equip., 82 F.3d 1194, 1202 (1st Cir. 1996)). Additionally, the disclosed risks relating to future sales of Apligraf, (Stein Memo., p. 9), ensured that investors could not reasonably have any expectations as to future results based on historical information. Finally, as Plaintiffs allege, sales of Apligraf did actually increase by 400% after this statement was made and during the class period.

B. December 2, 1999 Press Release: “The growth in Apligraf Sales now being seen is due to new Apligraf marketing sales initiatives by Novartis.”

This statement is not misleading as a matter of law, under the principle described above in Cytoc, Parametric, Boston Tech., and Polaroid, because Plaintiffs have failed to allege that the marketing and sales initiatives had no impact on the growth of Apligraf sales.

C. February 14, 2000, Amended Form 10-Q: “In the opinion of management the accompanying consolidated financial statements include all adjustments...necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented.”

Plaintiffs allege that the February 14, 2000 Amended Form 10-Q was incomplete because it failed to disclose various “material adverse factors.” (Chart, p. 4).

First, this statement was made only after Mr. Stein resigned his position as CEO and Chairman of the Board. Not only do Plaintiffs fail to cite any case where an individual was held liable for a statement after he left management, but Plaintiffs do cite Serabian, which as discussed above, was a decision where the First Circuit dismissed claims against an individual who, like Mr. Stein, was only the company’s CEO and Chairman of the Board for the very beginning of the class period.

Second, this broad, conclusory allegation regarding the failure to disclose various material adverse factors fails for the reasons recited throughout this Reply, Stein’s Memorandum, Co-Defendants’ Memorandum, and Co-Defendants’ Reply. Plaintiffs general arguments about the failure to disclose alleged “material adverse factors” even fails under the very same authority they attempt to rely upon. Cabletron, 311 F.3d at 36 (finding that statements were not materially misleading when made because the complaint failed to demonstrate that the alleged “problems” with a product “were known to the individual defendants by mid-March, when the first two statements were made”).

D. February 14, 2000, Amended Form 10-Q: “We expect production volume to increase and our margins to improve. We expect to continue to expand manufacturing operations.”

This Reply and Stein’s Memorandum already include substantial analyses as to why these statements are not actionable.

E. February 24, 2000 Press Release: A “strong interest in the Company” led to the oversubscription of Organogenesis’ stock offering.

Again, as above, this statement cannot be used against Mr. Stein because it was only made after he left the Company. This statement is not misleading as a matter of law under Cytec, Parametric, Boston Tech., and Polaroid because Plaintiffs have failed to allege that “strong interest in the company” had nothing to do with the oversubscription of Organogenesis’ stock offering.

V. Plaintiffs’ Opposition Makes No Cogent Argument for Scierter

Plaintiffs’ Opposition fails to describe why the Complaint creates any inference of scierter at all -- let alone a strong inference. Plaintiffs rely primarily on cases involving sales of stock by insiders. But what Plaintiffs ignore is that they have not alleged that Mr. Stein made any sales when he was with Organogenesis. Plaintiffs have also failed to demonstrate that Mr. Stein made any false statements with knowledge of that falsity.

A. Plaintiffs Failed to Distinguish Cases Mr. Stein Cited Directly on Point.

Not only do Plaintiffs fail to cite any authority for the proposition that the registration to sell stock alone creates any inference of scierter, but they fail to effectively distinguish Mr. Stein’s authority that the mere registration of stock alone does not create any such inference. Bay v. Palmisano, Nos. Civ. A. 01-0949, 01-1509, 01-1510, 01-1801, 2002 WL 31415713 *10 n.16 (E.D. La. Oct. 24, 2002). Furthermore, Plaintiffs completely fail to address Mr. Stein’s position that even if he did sell the stock he registered to sell, the decision in Greebel v. FTP Software, Inc., 194 F.3d 185 (1st Cir. 1999) is directly on point. As Mr. Stein stated in his Memorandum, the court in Greebel held that that sales by a former officer during the class period amounting to \$19 million out of the \$20 million of his total stock sales was not suspicious, as a matter of law. Id. at 206. The Greebel court explained: “[i]t is not unusual for individuals leaving a company, like [defendant], to sell shares.” Id.

B. Plaintiffs Have Not Alleged That Mr. Stein Made Any Statements While Knowing That They Were Misleading, and Plaintiffs Cannot Invoke Group Knowledge to Establish Scienter Against Mr. Stein.

For reasons discussed throughout this Reply and Mr. Stein's Memorandum, Plaintiffs have failed to allege that supposed "material adverse conditions" actually existed when Mr. Stein made his alleged statements, or that, even if they did exist, Mr. Stein was aware of these "material adverse factors" at the time he spoke. Plaintiffs' failure to demonstrate that Mr. Stein spoke with knowledge of falsity undermines any attempt to establish scienter.

Plaintiffs do attempt to claim that this Court can infer that Mr. Stein had knowledge of the "material adverse factors" effecting Apligraf because of his position in the Company. (Opposition, pp. 46-48). But Plaintiffs argument has several flaws when applied to the facts of this case.

First, as explained above, this argument based on group knowledge does not eliminate the requirement that scienter be determined by an examination of each individual and the context of each individual's alleged statements. For this reason alone, Plaintiffs' argument cannot be used against Mr. Stein because Plaintiffs have made no individual or particularized allegations that Mr. Stein made any false, actionable statements, let alone that he had any knowledge of falsity when he did allegedly speak.

Plaintiffs have also failed to allege that any of the "material adverse factors" effected the Company's core operations. Many of the alleged "material adverse factors" were peripheral issues regarding specific day-to-day details of product sales and distribution, which was exclusively handled by Novartis not Organogenesis, and quality control issues, which Plaintiffs specifically allege was overseen by individuals other than Mr. Stein. (Compl. ¶ 62(a)).

Finally, in contrast to Plaintiffs' authority from other jurisdictions on this matter, the law in this District is clear that "scienter is not sufficiently pleaded by alleging that the defendants must have known the facts solely by virtue of their positions with the issuer of the securities." In re Stone & Webster, Inc. Sec. Litig., 253 F. Supp. 2d 102, 130 (D. Mass. 2003) (internal quotations

and citations omitted); see also In re Galileo Corp. S'holder Litig., 127 F. Supp. 2d 251, 261 (D. Mass. 2001); In re Peritus Software Serv., Inc. Sec. Litig., 52 F Supp. 2d 211, 228 (D. Mass. 1999); Lirette v. Shiva Corp., 27 F. Supp. 2d 268, 283 (D. Mass. 1998).

Moreover, the facts alleged in this case do not present the rare and exceptional circumstances presented in the authority from other jurisdictions relied upon by Plaintiffs where inferences of scienter were based on allegations of control. See Marksman Partners, LP v. Chantal Pharm. Corp., 927 F. Supp. 1297, 1314 (C.D. Cal. 1996) (relying on circumstantial evidence of scienter based on defendants' access to, control, and approval of financial statements containing massive accounting fraud involving millions of dollars of inflated sales figures); In re Sears, Roebuck & Co. Sec. Litig., 291 F. Supp. 2d 722, 727 (N.D. Ill. 2003) (finding evidence of scienter based on specific statements made by individual defendants demonstrating that they were familiar with the credit card portfolio that was the basis of the alleged fraud, and which represented \$1.5 billion of the company's \$2.202 billion operating income).

VI. No Control Person Violations Have Been Alleged During Mr. Stein's Tenure at Organogenesis

Plaintiffs' attempt to plead a Section 20(a) control person claim against Mr. Stein fails for several reasons. To state a claim under Section 20(a), a plaintiff must plead "(1) an underlying violation by a controlled person or entity; and (2) that a defendant controlled the violator." Garvey v. Arkoosh, 354 F. Supp. 2d 73, 85 (D. Mass. 2005). While this Circuit has not explicitly addressed the issue, see Aldridge v. A.T. Cross Corp., 284 F.3d 72, 85 (1st Cir. 2002) (denying control person liability on separate grounds), at least two other Circuits require that plaintiffs also allege culpable participation in the alleged fraud. E.g., SEC v. First Jersey Sec., Inc., 101 F.3d 1450, 1472 (2d Cir. 1996); Rochez Bros., Inc. v. Rhoades, 527 F.2d 880, 885 (3d Cir. 1975).

In the current case, Plaintiffs have failed to allege any of these three required elements against Mr. Stein. First, for the reasons discussed in Mr. Stein's Memorandum, this Reply, Co-

Defendants' Memorandum, and Co-Defendants' Reply, Plaintiffs have failed to allege a primary violation by either Organogenesis or any of the other defendants. Second, Plaintiffs have failed to make any allegations that Mr. Stein "controlled" Organogenesis or any other defendant during the class period. While Plaintiffs do make some general, conclusory allegations of control based on the defendants' "positions of control and authority as officers and directors of the Company," (Compl. ¶ 38), it is well-established that such allegations based on officer or director status alone are insufficient for pleading a Section 20(a) violation. E.g., Ellison v. Am. Image Motor Co., Inc., 36 F. Supp. 2d 628, 642 (S.D.N.Y. 1999); In re Livent, Inc. Sec. Litig., 78 F. Supp. 2d 194, 222 (S.D.N.Y. 1999) ("Officer or director status alone does not constitute control" for purposes of Section 20(a)).

Furthermore, in alleging a control person violation against Mr. Stein, Plaintiffs are once again ignoring their own allegations that Mr. Stein resigned as CEO and Chairman after the first two months of the over two year class period. Even if Mr. Stein's "control" could be premised on his status alone, which it cannot, the fact that he only held his positions for such a short period demonstrates that he cannot possibly be alleged to have had any control whatsoever of Organogenesis or any other defendant for a vast majority of the class period.

Finally, as discussed throughout this Reply and Mr. Stein's Memorandum, Plaintiffs have failed to provide any sufficient allegations supporting the argument that Mr. Stein acted with any type of scienter or culpability.

CONCLUSION

For the reasons stated above, Mr. Stein respectfully requests this Court dismiss, with prejudice, all the claims against him in the Corrected Consolidated Amended Class Action Complaint.

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By his attorneys,

/s/ Breton Leone-Quick

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